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Environmental Assessment

I. Date: July 10, 2012

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IV. Description of the proposed action

A. Requested Approval

To obtain FDA approval of Pactiv's amended intended use of the previously cleared food contact substance methyl formate as a blowing agent for expanding polystyrene polymers that will be used in the manufacture of food contact articles.

B. Need for Action

Pactiv LLC uses the food contact substance (FCS) methyl formate (MF), as a blowing agent for the expansion of polystyrene (PS). MF is used in the same manner as other FDA-approved blowing agents, by being added during the extrusion process in the formation of PS foam sheet from which various food contact articles are made. Pactiv currently has approval under FCN 630 to utilize MF as a blowing agent at up to 3% by weight (wt%) of the foaming formulation, either alone or in combination with other FDA-approved blowing agents.

Pactiv now seeks express approval to use MF to produce PS products that have a shorter hold time before use following their manufacture. MF is the same FCS as was approved for use as a blowing agent under FCN 630. Pactiv intends to

employ MF in the same manufacturing process to produce the same technical effect on the same types of products for use in connection with the same food types as was approved under FCN 630, except that Pactiv here intends to restrict its maximum use level of MF to 1.5 wt% of the foaming formulation in order to secure express approval of a shortened hold time in connection with manufacturing PS and laminated PS finished articles. Moreover, Pactiv's manufacturing under this requested approval will be subject to an annual overall production limit of [See Confidential Attachment Item 1] of such articles.

C. Location of Use

MF will be used in production plants that manufacture PS food contact articles in the U.S.

These facilities are located in Bakersfield, CA and Fresno, CA. Each facility is already subject to federal, state and local emission controls.

The Bakersfield and Fresno plants are subject to and comply with the Clean Air Act (42 U.S.C. §7401 et seq.) and Title V operating permits and other permit requirements that govern their operations. Neither facility has an aqueous discharge and as such there are no applicable National Pollutant Discharge Elimination System (NPDES) permits or pretreatment permits. All scrap material is recycled and the use of MF does not change the distribution of the solid waste stream for either facility.

The food contact materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the country.

D. Locations of Disposal

It is anticipated that disposal of the PS food contact articles containing MF will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency, for municipal solid waste in the U.S., excluding waste recovered for composting, generally 59.1% is land disposed, 12.8% combusted, and 28.2% was recovered for recycling (U.S. EPA, 2011). Only very small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food contact articles, in light of EPA regulations governing solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems (40 CFR Part 258), Existing landfills (constructed before October 9, 1993) do not have to be retrofitted to meet these requirements; however they must monitor groundwater and take corrective action if needed. Combustion of MF-containing PS products would be expected to release small amounts of carbon dioxide and water. MF contains no halogens, so it will not result in acid generation in an incineration facility.

Disposal environments, landfill locations, and environments adjacent to landfills are expected to be indistinguishable from those for food contact PS products currently in use. Therefore neither the use nor disposal of the MF-containing PS article will introduce any novel distribution of PS wastes. Also, as indicated in Table 3 of Narrative FCN Section II.F, any MF remaining in PS articles progressively diffuses from the article into the atmosphere with time. Therefore, atmospheric introduction of MF over all zones of PS end-use represents the most probable route of MF introduction into the environment.

V. Identification of substances that are the subject of the proposed action

MF, CAS#: 107-31-3, also known as formic acid methyl ester or methyl methanoate, is a colorless liquid with an ethereal odor. Its chemical formula is HCOOCH3.

The MF employed will be obtained from commercial sources that use conventional industrial methods of manufacture. The MF utilized will be of commercial grade, with a minimum purity of 97 wt%. The main constituent of the impurity is methanol, though trace amounts of water, at up to 0.05 wt%, and formic acid, at up to 10 ppm, may also be present.

Physical/Chemical Specifications

Molecular Weight: 60.05 g

Boiling Point: 32°C at 760 mmHg

Freezing Point: -100°C

Vapor Pressure: 585.7 mmHg at 25°C Liquid Density: 0.974 g/cm³ at 20°C Vapor Density relative to air: 2.1 Solubility in water: 33 wt% at 20°C

Source: ChemBioFinder Database, Methyl Formate, Available at http://www.chemfinder.com/chembiofinder/Forms/Search/ContentArea/ChemBioVizSearch.aspx?FormGroupId=8&AppName=CHEMBIOFINDER&AllowFullSearch=true&KeepRecordCountSynchronized=false&SearchCriteriald=4&SearchCriteriaValue=107-31-3&CurrentIndex=0

Hazardous Substances Data Bank, Methyl Formate, Chemical/Physical Properties, Available at http://toxnet.nlm.nih.gov/cgi-

bin/sis/search/f?./temp/~8DQTC3:1

VI. Introduction of Substances into the Environment

A. <u>Introduction of substances into the environment as a result of</u> manufacture

Notifier does not manufacture MF, rather it is obtained from commercial sources and used as a portion of the blowing agent mixture to foam PS for subsequent forming into containers, plates, and trays. To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of MF. Consequently, information regarding the manufacturing site and the manufacturer's compliance with relevant requirements is not provided here.

B. <u>Introduction of substances into the environment as a result of</u> use and disposal

MF was classified as a nonvolatile-organic-compound (VOC) by the United States Environmental Protection Agency (US EPA) in 2004. (Federal Register, Volume 69, Number 228, November 29, 2004). MF is non-HAP (Hazardous Air Pollutant), has no effect on the stratospheric ozone (i.e. it has zero ODP [Ozone Depletion Potential]), and does not cause global warming (i.e. it has zero GWP [Global Warming Potential]).

Use

MF is used as a blowing agent for polystyrene foam. MF is a substitute for hydrocarbon VOC foaming agents that do have adverse effects on the environment with respect to air quality. MF is released to the air at several points of the manufacturing process.

[See Confidential Attachment Item 2 for manufacturing details.]

The manufacturing process does not result in any other waste streams containing MF. No water or landfill is exposed to MF, and all internal waste is recycled internally with MF being captured by a 99% efficient emissions control device.

After consumer use, MF containing products are ultimately discarded as normal trash for disposal in landfills or incineration facilities after consumer use. Replacing VOC blowing agents with MF will not alter the amount or distribution of PS wastes. In the event that MF containing materials reach a landfill, the Henry's law constant shows it will be released to the air from water or soil. The high internal temperature of landfills will also promote release or hydrolysis of the MF. MF contains no halogens, so it will not result in acid generation in an

incineration facility. The proposed usage of MF is also trivial compared to the 250 million tons of waste generated per year in the US. [Source: http://www.epa.gov/osw/nonhaz/municipal/index.htm.]

Using data from Table 6 in the Narrative FCN, Section II.G, and assuming a worst case scenario of all MF being released at the manufacturing facility, the production limits and maximum MF emissions are tabulated as follows in **EA Table 1**:

[See Confidential Attachment Item 3]

While global effects on air quality are influenced from all MF emission sources, local regions are going to have higher MF exposure. Food Service items and Food Packaging articles are manufactured at two different facilities that are a significant distance apart (177 km) such that there is no overlap in their emissions. For this EA, the evaluation is based upon the facility with the highest emissions (Food Service) to produce the worst-case exposure estimates. This represents a worst-case exposure compared to any subsequent post-consumer use.

As presented in EA Table 1 (Confidential Attachment Item 3), a worst-case calculation of MF emissions from the Food Service facility is [See Confidential Attachment Item 4]. These emissions would partition to air, water, soil and sediment surrounding the facility based upon the environmental fate properties of MF and of the surrounding environment. An accepted way to model the partitioning of chemicals in the environment is through the use of the Level III EQC (Fugacity) Model. This tool is part of EPI Suite (U.S. EPA, 2000 – 2011), the Estimation Programs Interface (EPI) Suite M which was developed by the U.S. Environmental Protection Agency's Office of Pollution Prevention and Toxics and Syracuse Research Corporation as a tool to screen chemicals for release potential (http://www.epa.gov/oppt/exposure/pubs/episuite.htm). In general, fugacity models predict the partitioning of an organic compound in an evaluative environment. A Level III model assumes steady-state but not equilibrium conditions. The Level III model in EPI Suite predicts partitioning between air, soil, sediment and water using a combination of default parameters and various input parameters that may be user defined or estimated by other programs within EPI Suite.

For this assessment, the default parameters for the physico-chemical properties of MF residing in EPI Suite were used. These values agreed closely with those presented earlier in this document (for example, boiling point of 31.7 °C, vapor pressure of 586 mm Hg, and water solubility of 230,000 mg/L). Of the user-input values, only the default of equal emissions to air, water and soil was

revised to consist of zero emissions to water or soil (consistent with facility operations, as there is no discharge to water and all scrap is internally recycled) but emissions of MF [See Confidential Attachment Item 4] to air (consistent with worst case calculations). The output of the Level III EQC model indicated that, given these conditions, the distribution of the emitted MF would be as follows: 93.3% to air, 6.05% to water, 0.608% to soil, and 0.0116% to sediment. Thus, of the [See Confidential Attachment Item 4] emissions, 6.05% or [See Confidential Attachment Item 5] would partition to water.

One approach to determining the resulting concentration in water, if there were aqueous discharges (which do not exist for either production facility) is to base the calculations on the default environment in the Level III EQC Model. The evaluative environment of this model is an area of 100,000 km², which is regarded as being typical of a jurisdictional or ecologically homogeneous region of approximately the size of the state of Ohio. The corresponding volume of water evaluated in the model is 2 x 10¹¹ m³ (Mackay et al., 1996). Assuming [See Confidential Attachment Item 5] entered this water volume, under steady state conditions, the resulting water concentration of MF would be 3.67 x 10⁻⁷ mg/L. Note that no water discharges of any kind actually occur from either facility; this calculation is merely an estimate of a water concentration if the atmospheric emissions were distributed to water in a proportion determined by the environmental fate properties of MF. Although MF is water soluble, it is also extremely volatile; thus, the primary environmental fate compartment is air, as discussed previously.

An additional tool was used to provide a more localized worst-case estimate of aqueous emissions, if they were to occur. Estimation of MF exposure to aquatic organisms was performed using the Exposure and Fate Assessment Screening Tool, Version 2.3. (E-FAST V2.0), which is a screening-level computer tool developed to support U.S. EPA assessments of potential exposures to chemicals (http://www.epa.gov/oppt/exposure/pubs/efast2man.pdf). This tool does not estimate physical-chemical properties, environmental fate parameters, or environmental releases and requires these parameters from other sources. E-FAST uses default parameters and upper percentile parametric values and is considered to be a high-end estimate. Therefore, the model results are conservative estimations at the high end of (or higher than) concentrations that might actually be occurring in a real-world setting and the results should be evaluated with this in mind.

The General Population and Ecological Exposure module within E-FAST was selected to estimate the amount of chemical that could be released to surface water from the manufacturing site with the highest release (Food Service). The module utilizes straight-forward removal and dilution assumptions. The input parameters include the known or estimated chemical releases into wastewater

during manufacturing (in reality absent in Pactiv's process), estimated proportion removed in typical wastewater treatment practices, and parameters associated with water treatment facilities and typical water body parameters. The chemical-specific inputs include the bioconcentration factor, molecular weight, and vapor pressure. Site-related inputs were obtained from model defaults for the Standard Industrial Classification (SIC) for "Plastic resin and fiber manufacturing" to provide an estimate of wastewater treatment and receiving stream parameters. The SIC industrial category incorporates further conservatism to the results as this parameter averages stream flow data from numerous facilities to calculate an average-case or high-end probability. E-FAST V2.0 calculates surface water concentrations for four streamflow conditions: harmonic mean, 7Q10, 30Q5 and 1Q10.¹ Finally, total days of release for expected manufacturing time-frames can be included in the model. A conservative estimate of 365 production days per year was used.

EA Table 2 (below) lists the input parameters used to calculate receiving water concentrations from worst-case methyl formate air emissions from the Food Service site. It was assumed that 6.05%, or [See Confidential Attachment Item 5], of the total emissions ([See Confidential Attachment Item 4]) remains to potentially enter the water after partitioning to the atmosphere, as explained previously. Extremely conservative assumptions of zero removal in wastewater treatment and zero binding to sludge were also made.

¹ The estimated mean and 7Q10 (lowest 7-consecutive day average flow that occurs every 10 years) flow values extracted from a Gage File database are used to estimate the harmonic mean (inverse daily flow), 1Q10 (lowest 1-day average flow that occurs every 10 years), and 30Q5 (lowest 30-consecutive day average flow that occurs every 5 years) flow values.

EA Table 2. Input values and assumptions for E-FAST General Population and Ecological Exposure Module

Parameter	Value	Source	
Bioconcentration factor	3.2 L/kg	EPI Suite, HSDB	
Molecular weight	60.05	HSDB, ChemBioFinder Database	
Vapor pressure	585.7 mm Hg at 25°C	EPISuite, HSDB, ChemBioFinder Database	
Wastewater treatment removal	0%	Conservative assumption	
Adsorption to wastewater treatment sludge	0%	Conservative assumption	
Drinking water treatment removal	0%	Conservative assumption	
SIC Code	Plastic resin and fiber manufacturing	E-FAST	
Release	[See Confidential Attachment Item 4]	Calculated	
Days per year of release	365	Conservative assumption	

The results are presented in EA Table 3 (below).

EA Table 3. Results of E-FAST General Population and Ecological Exposure Module: Aquatic Exposure Estimates (Surface Water, River Results)

	Aquatic Exposure Estimates – Surface Water (µg/L)				
Percentile	Harmonic Mean	30Q5	7Q10	1Q10	
10	1648	5350	9152	9866	
50	55.5	121	182	224	

The value for the 1Q10 is the appropriate result to compare to the acute toxicity data for ecological receptors; this is also the highest of the predicted EECs. The results indicate that the 50^{th} percentile (median) 1Q10 is 224 µg/L and the 10^{th} percentile 1Q10 is 9,866 µg/L. It must be emphasized that the concept of surface water concentrations is merely a theoretical exercise, as there are no discharges from either facility to surface water. The results are also derived from conservative assumptions based on high-end parameters and assumed to be higher concentration estimates than real-world scenarios.

EPI Suite and E-FAST reports are provided in **Confidential Attachment Items 6 and 7**, respectively.

For additional information regarding introduction of MF into the environment as a result of use in the manufacture of food contact articles, see **Confidential Attachment Item 8**, A Petition for VOC Exemption for Methyl Formate (CAS# 107-31-3), as submitted to California Air Resources Board by Pactiv Corporation (now Pactiv LLC).

VII. Fate of substances released into the Environment

MF quickly breaks down in the environment into its two breakdown products, methanol and formic acid. See **Confidential Attachment Item 8**.

Methyl Formate: Environmental Fate/Exposure Summary from Hazardous Substance Data Bank

Methyl formate's production and use as a food additive, solvent, and organic synthesis intermediate may result in its release to the environment through various waste streams. Methyl formate's use as a fumigant and

larvicide will result in its direct release to the environment. Methyl formate was identified as a flavor component in tomato fruit, as an aroma substance in apples, in the volatiles of chicken, beef, and pork flavor, and in brewed, roasted, and dried coffee.

If released to air, a vapor pressure of 5.9X10+2 mm Hg at 25 deg C indicates methyl formate will exist solely as a vapor in the atmosphere. Vapor-phase methyl formate will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 71 days (HSDB, 2012). Methyl formate did not undergo direct photolysis when irradiated with UV light >300 nm.

If released to soil, methyl formate is expected to have very high mobility based upon an estimated Koc of 25. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 2.2X10-4 atm-cu m/mole. Methyl formate may volatilize from dry soil surfaces based upon its vapor pressure.

If released into water, methyl formate is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 5.3 hours and 4.0 days, respectively. An estimated BCF of 3.2 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is expected to be an important fate process under environmental conditions with estimated half-life values of 5.1 and 12 days at pH values of 7 and 8, respectively. Using an experimentally-derived alkaline hydrolysis rate, the hydrolysis half-life of methyl formate was 67 hours, or 2.9 days, at pH of 7.0. Methyl formate was found to be readily biodegradable with 93% degradation after 28 days in the carbon dioxide headspace test following OECD TG 310 (SIAR, 2008).

Occupational exposure to methyl formate may occur through inhalation and dermal contact with this compound at workplaces where methyl formate is produced or used.

Monitoring data indicate that the general population may be exposed to methyl formate via inhalation of ambient air and ingestion of food and drinking water.

Source: Hazardous Substances Data Bank, March 2012. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+107-31-3

Formic Acid: Environmental Fate/Exposure Summary from Hazardous Substance Data Bank

Formic acid's production and use in textile dyeing, leather tanning, rubber production, as a chemical intermediate, as a solvent for perfumes and lacquers, in electroplating, silvering glass, and ore flotation, in the treatment of animal feeds, and as a food preservative and flavor adjunct may result in its release to the environment through various waste streams. It is widely used outside the U.S. as a silage additive. Formic acid occurs in fruits, vegetables, and leaves and roots of plants, and also in the secretions of numerous insects. It is also an intermediate product in the decomposition of organic matter in lake sediment and a photooxidation product of alkanes, alkenes, and biogenic terpenes by hydroxyl-radical and ozone-olefin reactions. Formic acid is also produced in clouds by the oxidation of formaldehyde by hydroxyl radicals, oxygen, or hydrogen peroxide. Formic acid is an intermediary human metabolite that is immediately transformed to formate.

If released to air, a vapor pressure of 42.6 mm Hg at 25 deg C indicates formic acid will exist solely as a vapor in the atmosphere. Vapor-phase formic acid will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 36 days. Formic acid does not absorb at wavelengths >290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight.

If released to soil, formic acid is expected to have very high mobility based upon an estimated Koc of 12. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 1.67X10-7 atm-cu m/mole. The pKa of formic acid is 3.8, indicating that this compound will primarily exist in anion form in the environment and anions generally do not adsorb more strongly to organic carbon and clay than their neutral counterparts. Formic acid may volatilize from dry soil surfaces based upon its vapor pressure.

If released into water, formic acid is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Theoretical BOD values ranging from 4.3% to 77.6% after 5 days using sewage, activated sludge, fresh water, and synthetic sea water inocula indicate that biodegradation may be an important environmental fate process. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 150 and 1,100 days, respectively. An estimated BCF of 3.2 suggests the potential for

bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

Occupational exposure to formic acid may occur through inhalation and dermal contact with this compound at workplaces where formic acid is produced or used.

Monitoring data indicate that the general population may be exposed to formic acid via inhalation of ambient air, ingestion of food, and dermal contact with this compound and other products containing formic acid. Formic acid is found in fruits and vegetables. Formic acid is widely detected in the atmosphere and in precipitation.

Source: Hazardous Substances Data Bank, March 2012. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+64-18-6

Methanol: Environmental Fate/Exposure Summary from Hazardous Substance Data Bank

Methanol's production and use as a solvent, fuel additive, and in the production of formaldehyde, acetic acid, and methyl tertiary butyl ether (MTBE) may result in its release to the environment through various waste streams. Methanol has been identified as a natural emission product from various plants and as a biological decomposition product of biological wastes and sewage.

If released to the atmosphere, a vapor pressure of 127 mm Hg at 25 deg C indicates that methanol will exist solely in the vapor phase. Vapor phase methanol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 17 days.

If released to soil, methanol is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 4.55X10-6 atm-cu m/mole. Methanol may also volatilize from dry soils based upon it vapor pressure. Biodegradation of methanol in soils is expected to occur rapidly based on half-lives in a sandy silt loam from Texas and a sandy loam from Mississippi of 1 and 3.2 days, respectively.

If released into water, methanol is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 3 and 35 days, respectively. Biodegradation is expected to occur in natural waters since methanol is degraded quickly in soils and was biodegraded rapidly in various aqueous screening tests using sewage seed or activated sludge. BCF values of less than 10, measured in fish suggests bioconcentration in aquatic organisms is low. Hydrolysis of methanol and photolysis in sunlit surface waters are not expected since methanol lacks functional groups that are susceptible to hydrolysis or photolysis under environmental conditions.

Occupational exposure to methanol may occur through inhalation and dermal contact with this compound at workplaces where methanol is produced or used.

Monitoring data indicate that the general population may be exposed to methanol via inhalation of ambient air, and ingestion of food and drinking water.

Source: Hazardous Substances Data Bank, March 2012. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+67-56-1

VIII. Environmental Effects of Released Substances

MF was assessed under the OECD HPV Chemicals Programme as part of the formates category, sponsored by the Formates Panel of the American Chemistry Council. The SIDS Dossiers and Testing Plan were reviewed by the US EPA and approval was given by the EPA to proceed to a SIAR (SIDS Initial Assessment Report). The following information was obtained largely from that SIAR, which was approved at SIAM 26, 15-18 April 2008 (http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=9B18D8C1-43FF-4865-BE6A-112EAC2233CA). The studies in the SIAR were rated the most reliable based upon completeness, protocol, GLP use, and other quality factors.

The formates category consisted of formic acid, five of its salts, and methyl formate. Because the salts (sodium formate, potassium formate, etc.) dissociate immediately in aqueous and biological matrices to the formate anion and corresponding cation, it was expected that the toxicological profiles of formic acid and the salts would be similar. Methyl formate was assessed separately because of its relatively slower hydrolysis (half life of 2.9 days at pH 7). However, since hydrolysis does occur, information on the aquatic toxicity of formic acid and

methanol are also presented. Ecotoxicity data for methyl formate, formic acid, and methanol are discussed below.

The aquatic toxicity of methyl formate has been investigated in studies conducted on organisms representing three important trophic levels: vertebrates, invertebrates, and plants. In a 96-hour static study with the golden orfe (Leuciscus idus), fish were exposed to nominal test concentrations of 0 (control) 10.0, 21.5, 46.4, 100.0, and 215.0 mg/L methyl formate. The 96-h LC₅₀ was calculated to be approximately 115 mg/L based on the nominal concentrations (BASF AG, 1989b). The acute toxicity of methyl formate was tested on the water flea, Daphnia magna in a static system at nominal concentrations of 0, 62.5, 125, 250, and 500 mg/L. There was no mortality, so the 48-h EC50 was > 500 mg/L, based on nominal concentrations (BASF AG, 1988e). With the marine amphipod Chaetogammarus maximus, a 96-h LC₅₀ of 320 – 560 mg/L was estimated (Adema and Bakker, 1984). In two different studies with green algae of the species Desmodesmus subspicatus, the 72-h EC₅₀s based upon yield (E_vC₅₀), which was the most sensitive parameter, were 258 and 223 mg/L, based upon nominal concentrations and when recalculated according to current guidelines (BASFAG, 1988g, 1989c, 1996; ECT, 2006b,c).

Information is also available on the toxicity of methyl formate to microorganisms. The EC₅₀ after 17 hours of exposure of *Pseudomonas putida* was > 10,000 mg/L (BASF AG, 1988h). The effect of methyl formate on the ciliate protozoan *Tetrahymena pyriformis* was investigated in a static test using photometric determination of population density as the endpoint. The 40-h EC₅₀ was determined to be 1,722 mg/L (Schultz et al., 2002; Netzeva et al., 2003).

Although no information was reported concerning effects of methyl formate on terrestrial plants, data are available for a terrestrial animal. A threshold narcotic concentration of 14.4 g/L of methyl formate was determined for tadpoles of the Northern Leopard Frog, *Rana pipiens* (Munch, 1972).

The EC $_{50}$ or LC $_{50}$ values for formic acid are between 1 and 100 mg/L. The toxicity of formic acid is apparently due to acidity, as demonstrated by a test with the fish Leuciscus idus where a neutralized test solution of 100 mg/L showed no toxicity (SIAR, 2008). According to the International Programme on Chemical Safety (ICPS,1997), methanol is of low toxicity to aquatic organisms, and effects due to environmental exposure to methanol are unlikely to be observed, except in the case of a spill. Due to its low toxicity, it is often used as a solvent in conducting studies on the aquatic toxicity of other chemicals. Aquatic toxicity data for methanol were summarized in the SIDS Initial Assessment Profile (SIAP) approved in 2004 (http://webnet.oecd.org/Hpv/UI/handler.axd?id=840a5b21-432b-488a-842c-283939c16175). In several 96-hour studies in fish in which methanol concentrations were measured during the tests, LC $_{50}$ s ranged from 15,400 to 29,400 mg/L. In Daphnia magna, 24-hour and 48-hour EC $_{50}$ s were > 10,000 mg/L (highest dose tested), with one value reported as 21,400 mg/L. In

aquatic plants, an EC $_{50}$ for growth inhibition of the green alga *Chlorella pyrenoidosa* was calculated to be 28,440 mg/L over 10-14 days.

Available data on the toxicity of methyl formate, formic acid and methanol to ecological receptors are summarized in **EA Table 4**.

EA Table 4. Ecotoxicity data or methyl formate, formic acid and methanol

Substance	Test organism	Test Result	Reference
Methyl formate	Fish (Leuciscus idus)	ca. 115 mg/L (96-h LC ₅₀)	BASF AG, 1989b
	Crustacean (Daphnia magna)	> 500 mg/L (48-h EC ₅₀)	BASF AG, 1988e
	Green algae (Desmodesmus	258 mg/L (72-h E _y C ₅₀)	BASF AG, 1988g; ECT, 2006b
	subspicatus)	223 mg/L (72-h E _y C ₅₀)	BASF AG, 1989, 1996; ECT, 2006b
	Bacteria (Pseudomonas putida)	>10,000 mg/L (17-h EC ₅₀)	BASF AG, 1988h
	Protozoa (Tetrahymena pyriformis)	1,722 mg/L (40-h EC ₅₀)	Schultz et al., 2002; Netzeva et al., 2003
	Frog (Rana pipiens)	14,400 mg/L (threshold narcotic concentration)	Munch, 1972
Formic acid	Fish (Leuciscus idus)	68 mg/L without neutralization; ≥ 100 mg/L with neutralization (96-h LC ₅₀)	BASF AG, 1989a
	Crustacean (Daphnia magna)	32.2 mg/L (48-h EC ₅₀). Toxicity at higher concentrations believed due to pH effect.	BASF AG, 1988d
	Green algae (Desmodesmus subspicatus)	24.7 mg/L (72-h E _y C ₅₀)	BASF AG, 1988f; ECT, 2006a
Methanol	Fish	15,400 to 29,400 mg/L (96-h LC ₅₀)	SIAP, 2004
	Crustacean (Daphnia magna)	> 10,000 mg/L (24-h and 48-h EC ₅₀	SIAP, 2004
	Green algae (Chlorella pyrenoidosa)	28,440 mg/L (10-14 d EC ₅₀)	SIAP, 2004

To characterize the risk of potential exposure of ecological receptors to MF, the ecotoxicity data are compared to the Expected Environmental Concentration (EEC). All of the emissions of methyl formate enter the atmosphere; however, ecological receptors are not considered to be atmosphere-dwelling. Typically, ecological receptors include inhabitants of the terrestrial and aquatic environments. As predicted by the Level III EQC model, only 0.61% of the atmospheric emissions of MF will partition to the soil compartment; this exposure pathway is therefore not considered further. The model predicts 93.3% of the MF will be in the air compartment and 6.05% will be in the water compartment. As discussed in Section VI of this EA, this percentage was used to derive the Expected Environmental Concentration (EEC) of MF in surface water using two different approaches. It is noted that there are no aqueous discharges from either manufacturing facility, so the EEC values for water are purely theoretical.

It was conservatively assumed that there would be no further treatment or degradation in surface water. Using the evaluative environment in the Level III EQC model, the EEC was 3.67×10^{-7} mg/L, a concentration many orders of magnitude below the toxicity levels for MF in **EA Table 4**. Using the E-FAST tool and a series of highly conservative assumptions, the worst-case EEC (1Q10 for the 10^{th} percentile) was $9.866 \, \mu \text{g/L}$ or $9.9 \, \text{mg/L}$. This value is an order of magnitude below the lowest LC50 for MF (115 mg/L) for fish. According to the Probabilistic Dilution Model tool in E-FAST, a concentration of 115 mg/L would be exceeded only 1 day per year. Given the highly conservative nature of the model itself and the input assumptions, this indicates that risks to ecological receptors in surface water are not expected from MF use in the present FCS.

IX. Use of Resources and Energy

MF, a non-VOC, is a substitute for hydrocarbon VOC foaming agents that do have adverse effects on the environment with respect to air quality.

X. Mitigation Measures

No significantly adverse environmental effects of use or disposal of the subject material have been identified. Therefore, no mitigation measures will be necessary.

XI. Alternatives to the proposed action

No significantly adverse environmental effects of use of disposal of the subject material have been identified. Therefore, no mitigation measures will be necessary.

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XIV. Attachments

Confidential Attachment to the Environmental Assessment

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